DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 12, 2015

Breathe Technologies
C/O Mr. Craig Coombs
President
Coombs Medical Device Consulting, Inc.
1193 Sherman St.
Alameda, CA 94501

Re: K141943/S003
Trade/Device Name: Breathe Technologies Life2000 Ventilation System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: June 8, 2015
Received: June 10, 2015

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Office of Device Evaluation
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141943

Device Name

Breathe Technologies Life2000 Ventilation System

Indications for Use *(Describe)*

The Breathe Technologies Life2000 Ventilation System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.
The ventilator is intended for use by qualified, trained personnel under the direction of a physician.

Specifically, the ventilator is applicable for adult patients who require the following types of ventilatory support:
- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control mode of ventilation.

The ventilator is suitable for use in home and institutional settings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Breathe Technologies 175 Technology Drive, Suite 100 Irvine, CA 92618 Tel: 949-988-7700 Contact: Samir Ahmad, Ph.D.
Correspondent Contact Information:	Craig Coombs President Coombs Medical Device Consulting, Inc 1193 Sherman St. Alameda, CA 94501 Office: 510.337.0140 Fax: 510.337.0416
Device Common Name:	Mechanical Ventilator
Device Classification & Name:	21 CFR 868.5895 Continuous Ventilator
Device Classification & Product Code:	Class II CBK
Device Proprietary Name:	Breathe Technologies Life2000 Ventilation System

Predicate Device Information:

Predicate Device:	LTV-1200
Predicate Device Manufacturer:	Pulmonetic Systems, Inc.
Predicate Device Premarket Notification #	K060647
Predicate Device Common Name:	Mechanical Ventilator
Predicate Device Classification & Name:	21 CFR 868.5895
Predicate Device Classification & Product Code:	Class II CBK

b. Date Summary Prepared

12 June 2015

c. Description of Device

The Breathe Technologies Life2000 Ventilation System is a portable, battery powered, critical care ventilator.

The Ventilator administers the physician-prescribed volume to the patient via the attached Breathe Technologies Patient Universal Connector which connects into the patient's tracheostomy tube, endotracheal tube, or any off the shelf non-invasive mask. It can also be used with the Breath Technologies NIOV Pillows Interface, a type of nasal mask.

The ventilator is small and light enough to be worn on a patient's belt, or slung over their shoulder. It is connected to a separate, third party, gas supply.

The Ventilator is intended for Institutional or Home Use. It is not intended for use during emergency/medical transportation.

d. Indications for Use

The Breathe Technologies Life2000 Ventilation System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is intended for use by qualified, trained personnel under the direction of a physician.

Specifically, the ventilator is applicable for adult patients who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control mode of ventilation.

The ventilator is suitable for use in home and institutional settings.

e. Comparison to Predicate Device

The Life2000 Ventilation System is substantially equivalent in Intended Use, Indications for Use, technology, and performance to the LTV-1200 that was cleared under K060647.

The Life2000 serves a subset of the cohort (adult) that are indicated for the LTV-1200 (patients >5kg).

The Life2000 has all the ventilation modes that are necessary for a critical care ventilator, whereas the LTV-1200 includes modes like SIMV and CPAP.

The Life2000 has a pneumatic active exhalation valve, whereas the LTV-1200 has a mechanical/pneumatic active exhalation valve.

Any technological differences between the Breathe Technologies Life2000 and the LTV-1200 can be determined to be clinically insignificant when compared to the reference device, the Breathe Technologies NIOV Ventilator, cleared under K103345.

The following table presents a comparison of the features of the predicate and applications devices, along with an analysis of why the resultant differences do not negatively impact a conclusion of substantial equivalence.

Tabular Comparison to Predicate Device

	Predicate Device: LTV-1200 K060647	**Application Device: Life2000 Ventilation System**	**Difference Status**
Indications for Use	The LTV 1200 ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11 lbs.), who require the following types of ventilatory support: - Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask). - Assist/Control, SIMV, CPAP, or NPPV modes of ventilation. The ventilator is suitable for use in institutional, home and transport settings.	The Breathe Technologies Life2000 Ventilation System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients who require the following types of ventilatory support: - Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask). - Assist/Control mode of ventilation. The ventilator is suitable for use in home and institutional settings.	The Indications for Use for the application device is a subset of the Indications for Use of the predicate. In particular, the application device treats only adult patients, rather than the predicate's >5kg limit. The application device does not have all the ventilation modes that the predicate device possesses. Finally, the application device is not indicated for use in emergency/medical transport settings.
Product Classification Code	CBK	CBK	Identical
CFR Citation	21 CFR 868.5895	21 CFR 868.5895	Identical
Principal Operator	Trained personnel under the direction of a physician	Trained personnel under the direction of a physician	Identical
Environment of Use	Institution, Home, and Transport	Institution & Home	Application device is not validated to work in an emergency/medical transport environment.
Patient Interface	Delivered invasively (via ET tube) or non-invasively (via mask).	Delivered invasively (via ET tube) or non-invasively (via mask).	Identical
Power Source	Battery Powered, can be run while battery is charging	Battery Powered, can be run while battery is charging	Identical
Operational Modes	Volume Control Volume Assist/Control Volume Assist Pressure Control Pressure Support SIMV CPAP NPPV	Volume Control Volume Assist/Control Volume Assist	The operational modes of the application device are a subset of the predicate.

	Predicate Device: LTV-1200 K060647	**Application Device: Life2000 Ventilation System**	**Difference Status**
Active Exhalation Valve?	Yes, Mechanical	Yes, Mechanical/Pneumatic	Clinically Equivalent
Design Designation	Portable Critical Care	Portable Critical Care	Identical
Size WxLxH (in)	3 x 10 x 12	3.2 x 7.7 x 1.0	The application device is much smaller than predicate device. Potentially easier for patient to handle. No new issues of S&E are raised by the size reduction
Weight	13.4 lbs	1.1 lbs	The application device is much smaller than predicate device. Potentially easier for patient to handle. No new issues of S&E are raised by the weight reduction.
Volume Setting Range	50 – 2000 ml/breath	50 – 750 ml/breath	The volume range of the application device is a subset of the predicate device
Resultant Tidal Volume	50 - 2000 ml/breath	50 - Up to 2000 ml/breath due to venturi effect	Identical
PEEP Setting	0 – 20 cmH2O	0 – 10 cmH2O	The PEEP range of the application device is a subset of the predicate device
PIP Alarms & Monitoring	Yes	Yes	Identical
Adjustable Inspiration Time	0.3 – 9.9 seconds	0.15 to 3 seconds	I-time of application device is a subset of predicate. Only clinically relevant times are used
Supply Gas	Oxygen, Air	Oxygen, Air	Identical
Method of supply gas pressurization	Internal turbine for Air Compressed Source for O_2	Compressed source for Air Compressed source for O_2	Clinically Equivalent Result from Ventilator
Sterilized?	Ventilator: No Patient Circuit: No	Ventilator: No Patient Circuit: No	Identical

f. Summary of Supporting Data

The Software Design and Validation process along with the bench testing of the device demonstrated that the Breathe Technologies Life2000 Ventilation System operates as intended.

In particular, testing demonstrated that Life2000 is compliant with the following Guidelines and Standards:

- ISO 10993-1 (2009): Biological evaluation of medical devices -- Part 1: Evaluation and Testing[1]
- FDA Draft Reviewer Guide for Ventilators (July 1995)
- ASTM F1246-91 (1991, Reapproved 2005); Standard Specification for Electrically Powered Home Care Ventilators, Part 1 – Positive Pressure Ventilators and Ventilator Circuits
- IEC 60601 – 1 (2005): Medical electrical equipment – General Requirements for Safety
- IEC 60601-1-2:2007 3rd Edition Medical Electrical Equipment- Part 1-2: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Compatibility- Requirements and Tests
- ISO 80601-2-12 (2011), First Edition 2011-04-15, Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

  The following additional testing was requested by the FDA to demonstrate Substantial Equivalence.
  - Ventilator Cleaning validation
  - Risk characterization of VOC's for most vulnerable patient population
  - Static Analysis Tool verification of software
  - Comparative Waveform Testing
  - Human Factors and Usability Testing with all intended cohorts and users.
  -

Breathe Technologies concludes from this comparison and the supporting data that the Breathe Technologies Life2000 Ventilation System is substantially equivalent to to the predicate Pulmonetic Systems LTV-1200 (K060647).

[1] Per Annex B.3, it was determined that all of the materials (and material processes) used in Life2000 are identical those in a reference device, the NIOV Ventilator and Accessories (K103345), except the polycarbonate material in the Universal Connector, which was shown to be identical to the polycarbonate used in the ResMed Ultra Mirage II Nasal Mask (K050359). This analysis was adopted for the Volatile Organic Compound and Particulate Matter testing.